

Patent claims

1. Aqueous preparation comprising an anti-EGFR antibody, a buffer, an amino acid and a surfactant.
2. Preparation according to Claim 1, characterised in that the antibody is cetuximab or EMD 72000 or one of the corresponding murine, humanised or chimeric antibody analogues.
3. Preparation according to Claim 2, characterised in that the antibody is cetuximab or EMD 72000.
4. Preparation according to one or more of Claims 1 to 3, characterised in that the buffer consists of one or more citrate salt(s), acetate salt(s), histidine salt(s), succinate salt(s), malate salt(s), phosphate salt(s) or lactate salt(s) and/or the respective free acid(s) or base(s) thereof or a mixture of one or more of the various salts and/or the acid(s) or base(s) thereof.
5. Preparation according to Claim 4, characterised in that the buffer consists of one or more citrate salt(s) and/or the free acid thereof, acetate salt(s) and/or the free acid thereof or L-histidine and/or an acid-addition salt thereof.
6. Preparation according to one or more of Claims 1 to 5, characterised in that the amino acid is L-arginine, glycine or L-methionine.
7. Preparation according to one or more of Claims 1 to 6, characterised in that the surfactant is a polyethylene sorbitan fatty acid ester or a polyoxyethylene-polyoxypropylene copolymer.

8. Preparation according to Claim 7, characterised in that the polyoxyethylene sorbitan fatty acid ester surfactant is polyoxyethylene (20) sorbitan mono-oleate or polyoxyethylene (20) sorbitan monolaurate.
- 5 9. Preparation according to Claim 7, characterised in that the surfactant is Poloxamer 407.
- 10 10. Preparation according to one or more of Claims 1 to 9, characterised in that an isotonicity modifier is furthermore present in a concentration necessary for isotonicity modification.
11. Preparation according to Claim 10, characterised in that the isotonicity modifier is sodium chloride.
- 15 12. Preparation according to one or more of Claims 1 to 11, characterised in that it has a pH of 5 – 7, preferably from pH 5.2 to pH 6.0.
13. Preparation according to Claim 12, characterised in that it has a pH of about 5.5.
- 20 14. Preparation according to one or more of Claims 1 to 13, characterised in that it comprises about 5 mg/ml of cetuximab or EMD 72000, about 10 mmol/l of citrate or histidine buffer, about 100 mmol/l of glycine, L-arginine or L-methionine, about 100 mmol/l of sodium chloride and about 25 0.01% of polyoxyethylene (20) sorbitan monooleate and has a pH of about 5.5.
- 30 15. Process for the preparation of a pharmaceutical preparation according to one or more of Claims 1 to 14, characterised in that an aqueous preparation comprising the anti-EGFR antibody is added to one of the said auxiliaries.

16. Use of the preparation according to one or more of Claims 1 to 14 for the treatment of tumour diseases.